MAY 1 4 2014 K133620 Page 1 of 3

DEXIS GENDEX Imaging Sciences International

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6 510(K) SUMMARY

Submitter:
Imaging Sciences International, LLC
also dba DEXIS LLC, Gendex Dental Systems
1910 North Penn Road, Hatfield PA 19440
Phone: 215-997-5666; Fax: 215-997-5665

Date of Summary: April 10, 2014

Contact person:

Ruth Pui, Sr. Regulatory Affairs Specialist
or
Sanjay Ahuja, Ph.D., Director, Regulatory Affairs

Device Name:

- Trade Name - i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System
- Common Name - X-ray, Tomography, Computed, Dental
- Classification name - Computed tomography x-ray system (21 CFR §892.1750, Product Code OAS)

Devices for Which Substantial Equivalence is Claimed:

- i-CAT Scanner, K061284
- GALILEOS Comfort Plus, K123070

Device Description:

i-CAT FLX was developed as an upgrade to the existing i-CAT Scanner. i-CAT FLX, manufactured by Imaging Sciences International, is a Cone Beam Volumetric Tomography and Panoramic X-ray dental imaging system that consists of a scanner and a software package for image reconstruction. It is a device in the i-CAT Scanner family. The components of the system include the main affixed unit, the overhead, the gantry, the tube head, the X-ray source assembly and collimator, the receptor panel, and software package for image reconstruction. The system is an open design that allows patients to sit upright during a procedure. An electric powered seat is built into the scanner for proper patient positioning.

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or neck. The proposed device utilizes cone beam X-ray technology, which

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generates conical x-ray beams that rotate around the patient's head and incident upon the receptor that generate sufficiently contrasted images. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. When interpreted by a trained physician, these images provide useful diagnostic information.

Indications for Use:

Devices of the i-CAT family consist of an x-ray system that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses), for use in planning and diagnostic support in adult and pediatric care.

Devices of the i-CAT family comprise a package of software modules capable of handling 2D and 3D data. This includes 3D reconstruction, storage, retrieval, viewing, and processing of 2D and 3D-image data.

The proposed indications for use above of i-CAT FLX include expansions into ENT (ear nose throat) region and pediatric care. The proposed device has been verified and validated to satisfy the requirements derived from the indications for use.

Summary of Technological Characteristics:

i-CAT FLX shares the same architectural components as both predicate devices including:

- An X-ray source on a motorized gantry
- Collimation of X-ray
- Two-dimensional (2D) X-ray detector
- A patient positioning and support system to ensure stability of the patient during scan.
- A software package which prepares and displays three dimensional (3D) reconstructions of the acquired data.

As evidenced through the Design Verification and Validation, i-CAT FLX can produce volumetric and panoramic images of the maxillofacial (including ENT) areas in the head, and they are of equivalent diagnostic quality as GALILEOS. The minor technological difference in the shape of image volumes does not affect imaging of the intended anatomical structures.

Based upon an analysis of the technological differences, and the substantiation through design verification and validation, ISI determines that the safety and effectiveness of the proposed i-CAT FLX is substantially equivalent to the predicate devices, i-CAT Scanner (K061284) and GALILEOS Comfort Plus (K123070) and does not raise any new concerns.

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Non-Clinical Test Data:

Performance bench testing was conducted as part of design control to ensure the safety and effectiveness of i-CAT FLX is equivalent to the predicate devices. The safety and effectiveness of i-CAT FLX for the proposed indications for use is substantiated through verification and validation testing on two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and maxillofacial areas, for use in planning and diagnostic support in adult and pediatric care. The use of i-CAT FLX for pediatric care, including considerations for proper positioning of pediatric patients for image acquisition, has also been verified and validated. Biocompatibility evaluation was conducted on patient contacting accessory parts and found to be in conformance with ISO 10993-5 and ISO 10993-10. EMC and Electrical Safety testing on i-CAT FLX was performed by Intertek Testing Services and found to meet all the requirements in standards IEC 60601-1: 2005, IEC 60601-1-6:2010, IEC 62366:2007, IEC 60601-2-63:2012 and IEC 60601-1-2:2007.

Clinical Test Data:

Sample clinical images acquired using i-CAT FLX were reviewed to be of acceptable clinical effectiveness for the proposed indications for use.

Conclusion:

Based on the comparison of intended use, design, technological characteristics, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, the minor differences between i-CAT FLX device, and the predicate devices, i-CAT Scanner (K062184) and GALILEOS Comfort Plus (K123070), do not raise new concerns in safety and effectiveness for the proposed indications of use. ISI concludes that i-CAT FLX is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

Imaging Sciences International
% Ms. Ruth Pui
Sr. Regulatory Affairs Specialist
1910 North Penn Road
HATFIELD PA 19440

Re: K133620
Trade/Device Name: Cone Beam 3D and 2D Panoramic Dental Imaging System (i-CAT FLX)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: April 11, 2014
Received: April 14, 2014

Dear Ms. Pui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133620

Device Name
i-CAT FLX, Cone Beam 3D and 2D Panoramic Dental Imaging System

Indications for Use *(Describe)*
Devices of the i-CAT family consist of an x-ray system that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses), for use in planning and diagnostic support in adult and pediatric care. Devices of the i-CAT family comprise a package of software modules capable of handling 2D and 3D data. This includes 3D reconstruction, storage, retrieval, viewing, and processing of 2D and 3D-image data.

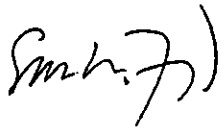
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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